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TENT COOPERATION TRE, Y

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 30 November 1999 (30.11.99)	<b>Applicant's or agent's file reference</b> 183-109(PCT)
<b>International application No.</b> PCT/US99/04412	<b>Priority date (day/month/year)</b> 17 March 1998 (17.03.98)
<b>International filing date (day/month/year)</b> 01 March 1999 (01.03.99)	
<b>Applicant</b> MARGOLIN, Solomon, B.	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

18 October 1999 (18.10.99)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Jean-Marie McAdams Telephone No.: (41-22) 338.83.38
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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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RECD 27 APR 2000

Applicant's or agent's file reference 183-109(PCT)	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/04412	International filing date (day/month/year) 01 MARCH 1999	Priority date (day/month/year) 17 MARCH 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/445 and US Cl.: 514/315, 327		
Applicant MARGOLIN, SOLOMON B.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets.  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
 These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  18 OCTOBER 1999	Date of completion of this report  06 APRIL 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  KEVIN E. WEDDINGTON
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/04412

**I. Basis of the report****1. With regard to the elements of the international application:\***☒ the international application as originally filed☒ the description:pages 1-23

, as originally filed

pages NONE

, filed with the demand

pages NONE

, filed with the letter of \_\_\_\_\_

☒ the claims:pages 24-29

, as originally filed

pages NONE

, as amended (together with any statement) under Article 19

pages NONE

, filed with the demand

pages NONE

, filed with the letter of \_\_\_\_\_

☒ the drawings:pages NONE

, as originally filed

pages NONE

, filed with the demand

pages NONE

, filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:pages NONE

, as originally filed

pages NONE

, filed with the demand

pages NONE

, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/04412

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)	Claims <u>1-18</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-18</u>	NO
Industrial Applicability (IA)	Claims <u>1-18</u>	YES
	Claims <u>NONE</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-18 meet the criteria set out in PCT Article 33(2) as having novelty in the pharmaceutical art.

Claims 1-18 meet the criteria set out in PCT Article 33(4) as having industrial applicability in the pharmaceutical art.

Claims 1-18 lack an inventive step under PCT Article 33(3) as being obvious over Gadekar, Clough et al. (US 5,179,098) or Clough et al. (US 5,314,892).

The three references, each individually, teach the applicants' instant compounds, 2-(1H) pyridones antifungal agents.

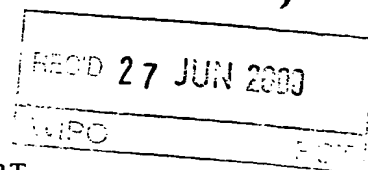
The instant invention differs from the cited references in that the cited references do not teach the specific amounts of the active compound and the carriers as set forth in claims 7-9 and 16-18. However, to determine an amount of the active compound having optimum effect against fungi is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine optimum amounts to get the maximum effect of the active compound.

\_\_\_\_ NEW CITATIONS \_\_\_\_\_  
NONE

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 183-109(PCT)	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/04412	International filing date (day/month/year) 01 MARCH 1999	Priority date (day/month/year) 17 MARCH 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/445 and US Cl.: 514/315, 327		
Applicant MARGOLIN, SOLOMON B.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets.  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
These annexes consist of a total of 0 sheets.
- This report contains indications relating to the following items:
  - ☒ Basis of the report
  - ☐ Priority
  - ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☐ Certain observations on the international application

**CORRECTED  
VERSION**

Date of submission of the demand 18 OCTOBER 1999	Date of completion of this report 31 MAY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer. KEVIN E. WEDDINGTON Telephone No. (703) 308-1235

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/04412

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

☒ the international application as originally filed☒ the description:

pages 1-23 , as originally filed  
pages NONE , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_

☒ the claims:

pages 24-29 , as originally filed  
pages NONE , as amended (together with any statement) under Article 19  
pages NONE , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_

☒ the drawings:

pages none , as originally filed  
pages NONE , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:

pages NONE , as originally filed  
pages NONE , filed with the demand  
pages NONE , filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE  
☒ the claims, Nos. NONE  
☒ the drawings, sheets/fig NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/04412

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)	Claims <u>1-18</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>7-9 and 16-18</u>	YES
	Claims <u>1-6 and 10-15</u>	NO
Industrial Applicability (IA)	Claims <u>1-18</u>	YES
	Claims <u>NONE</u>	NO

**2. citations and explanations (Rule 70.7)**

The following statements are set forth responsive to Applicant's response to the Written Opinion and upon further consideration.

Claims 1-18 meet the criteria set out in PCT Article 33(2) as having novelty in the pharmaceutical art.

Claims 7-9 and 16-18 meet the criteria set out in PCT Article 33(3) as having an inventive step in the pharmaceutical art since the prior art does not teach the applicants' specific amounts of the active compounds and carriers.

Claims 1-18 meet the criteria set out in PCT Article 33(4) as having industrial applicability in the pharmaceutical art.

Claims 1-6 and 10-15 lack an inventive step under PCT Article 33(3) as being obvious over Gadekar, Clough et al. (US 5,179,098) or Clough et al. (US 5,314,892).

The three references, each individually, teach the applicants' instant compounds, 2-(1H) pyridones antifungal agents can be formulated into various compositions.

----- NEW CITATIONS -----

NONE

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/04412

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61K 31/445

US CL :514/315, 327

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/315, 327

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
CAS-ONLINE, APS

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,974,281 A (GADEKAR) 10 August 1976, see the entire document.	1-18
X	US 5,179,098 A (CLOUGH et al.) 12 January 1993, see the entire document.	1-18
X	US 5,314,892 A (CLOUGH et al.) 24 May 1994, see the entire document.	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

<p>* Special categories of cited documents:</p> <p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document published on or after the international filing date</p> <p>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the international filing date but later than the priority date claimed</p>		<p>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>*G* document member of the same patent family</p>	
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Date of the actual completion of the international search

05 MAY 1999

Date of mailing of the international search report

14 MAY 1999

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*CJB*